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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,741	10/10/2001	Om Reddy Gaddam	U 013662-3	8734
140	7590	02/25/2005	EXAMINER	
LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023				RAO, DEEPAK R
		ART UNIT		PAPER NUMBER
		1624		

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/975,741	GADDAM ET AL.
	Examiner Deepak Rao	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 November 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3,5-10,12-31 and 35-82 /are pending in the application.
- 4a) Of the above claim(s) 3,5,6,12-26,35-77 and 79-82 /are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,7-10,27-31 and 78 /are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

**DETAILED ACTION**

This office action is in response to the amendment filed on November 19, 2004.

Claims 1, 3, 5-10, 12-31 and 35-82 are pending in this application.

***Election/Restrictions***

The elected invention of Group I, claims 1, 7-10, 27-31 and 78 are under consideration.

Claims 3, 5-6, 12-26, 35-77 and new claims 79-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

***Withdrawn Rejections/Objections:***

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

***The following rejections are maintained:***

Claims 1, 7-10, 27-31 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray et al., WO 99/20614 in view of Claussner et al., U.S. Patent No. 5,646,172. The reasons provided in the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'the compounds of Claussner differ structurally from the compounds of formula (I) and they are used for a different purpose'. This is not found to be persuasive because the primary reference, Lohray (WO'614) teaches the compounds of formula (I) and the corresponding pharmaceutically acceptable salts thereof, including salts of the carboxylic acid moiety formed by organic bases such as lysine, guanidine, etc. The secondary reference Claussner in the analogous art of pharmaceutical compounds teaches the equivalency of various organic bases that are used in forming pharmaceutically acceptable salts of a given carboxylic acid. The secondary reference is introduced merely to show that one skilled in the art would have been motivated to select any of the organic bases including those of the instant claims, to form the pharmaceutically acceptable salt of the instant claims. Where the specific compound falls within the ambit of a "very limited number of compounds", the fact that a specific embodiment is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered." *In re Lamberti*, 545 F.2d 747,750, 192 USPQ 278, 280 (CCPA 1976). "The question under 35 U.S.C. 103 is not merely what the reference expressly teaches but what it would have suggested to one of ordinary skill in the art at the time the invention was made."

Applicant argues that the data shown for compound of Example 30 of WO'614 vs. Example 2 of the instant application establishes an advantage of the claimed compounds. However, objective evidence of nonobviousness must be presented in an appropriate affidavit or declaration. Attorney arguments cannot take the place of the evidence. For these reasons, the rejection is maintained.

***The following rejections are under new grounds:***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7-10 and 27-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. The structural formula in claim 1 is confusing. The compound represented by the structure within the parenthesis is an uncharged carboxylate, however, when considered along with the parenthesis and  $p^-$ , it represents a charged compound. However, it is not clear where the ‘charge’ is. Further, this can also be a doubly charged species because p can be 1 or 2 and it is not clear where the two ‘charges’ are intended.
2. Claim 7 recites the limitation "..... propanoic acid lysine salt" in each of the species 1-6. There is insufficient antecedent basis for this limitation in claim 1 on which claim 7 is dependent. Claim 1 does not list M to represent “lysine”.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

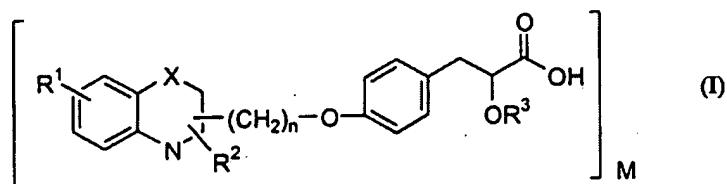
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 7, 27, 28, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Lohray et al., WO 99/20614. The instant claims read on reference disclosed compounds and the salts thereof. See formula (I) in page 1, and the corresponding species in the Examples 29, 30, etc. The reference teaches pharmaceutically acceptable salts include alkali metal salts and salts of organic bases such as lysine, arginine, etc. see page 15, lines 25-32.
2. Claims 1, 7-10, 27-31 and 78 are rejected under 35 U.S.C. 102(a) as being anticipated by Lohray et al., WO 00/66572. The instant claims read on reference disclosed compounds and the salts thereof. See formula (I) in page 1 and the corresponding species of the Examples. The reference teaches that the pharmaceutically acceptable salts include those derived from organic bases such as glucamine, methylglucamine, dicyclohexylamine, benzylamine, substituted guanidine, lysine, arginine, etc., see the disclosure in page 17, starting at line 25.

Applicant cannot rely upon the foreign priority papers based on the Indian Patent Application filed on October 12, 2000 to overcome this rejection because the priority document does not fully support the compounds of structural formula of the instant claims. The priority document discloses a structural formula (depicted below for convenience) which is different from that disclosed in claim 1 of the instant application.

general formula (I)



Specifically, the priority document does not disclose the presence of di-salts intended by the recitation " p " in the instant claims.

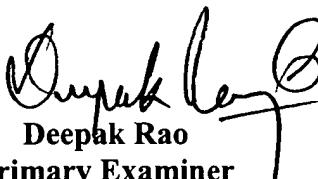
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Deepak Rao  
Primary Examiner  
Art Unit 1624

February 21, 2005